

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SEPRACOR, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-113-JJF
	)	(Consolidated)
DEY, L.P. and DEY, INC.,	)	
	)	
Defendants.	)	
	)	
<hr/> SEPRACOR, INC.,	)	<b><u>REDACTED</u></b>
	)	<b><u>PUBLIC VERSION</u></b>
Plaintiff,	)	
	)	
v.	)	
	)	
BARR LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**DECLARATION OF SAM V. DESAI IN SUPPORT OF DEFENDANTS  
DEY, L.P. AND DEY, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF**

**(VOLUME IV – EXS. 25-27)**

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*Attorneys for Defendants  
Dey, L.P. and Dey, Inc.*

Dated: May 1, 2008

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SEPRACOR, INC.,	)	C.A. No. 06-113 (JJF)
	)	(Consolidated)
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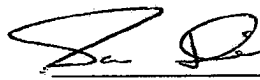
I, Sam V. Desai, am a member of the law firm Frommer Lawrence & Haug LLP, counsel for Defendants, Dey, L.P. and Dey, Inc. I make this declaration in support of DEFENDANT'S DEY, L.P. AND DEY, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF.

1. Attached as Exhibit 25 is a chart summarizing the parties' proposed constructions.
2. Attached as Exhibit 26 is a true and accurate copy of the Supplemental Report of Richard C. Ahrens, M.D, dated January 17, 2008 (filed under seal).
3. Attached as Exhibit 27 is a true and accurate copy of a March 26, 1999 letter from Joan Hankin, J.D., Regulator Review Officer, Division of Drug Marketing, Advertising, and

Communications at the Food and Drug Administration to Mr. James Allen Wachholz, Senior Director, Regulatory Affairs at Sepracor, Inc.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 1, 2008

  
\_\_\_\_\_  
Sam V. Desai

# **EXHIBIT 25**

# Exhibit 25

## US PATENT NO. 5,362,755

DISPUTED TERMS (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEV'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"while reducing side effects associated with chronic administration of racemic albuterol" (claim 1)	The side effects are those associated with chronic administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Reducing those beta-adrenergic side effects and teratogenic effects associated with the periodic or prophylactic administration of albuterol that are caused directly by the S(+) enantiomer of albuterol.	"Side effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.
"while simultaneously reducing undesirable side effects" (claim 1)	The side effects are those associated with chronic administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic side effects and teratogenic effects associated with the use of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol.	"Side effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.
"chronically administering" (claim 1)	"Chronic administration" and "chronically administering to the individual" mean to administer the drug to a human on a recurring basis to prevent or reduce the extent to which bronchospasms occur.	Treating periodically or prophylactically.	"Chronic" should mean "prophylactic or periodic."

00540601

# Exhibit 25

## US PATENT NO. 5,547,994

DISPUTED TERM (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEV'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"while reducing side effects associated with the acute administration of racemic albuterol" (claim 1)	The side effects are those associated with acute administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Reducing those beta-adrenergic side effects and teratogenic effects associated with the administration of racemic albuterol to a patient after the onset of an asthma attack that are caused directly by the S(+)-enantiomer of albuterol.	"Side effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.
"while simultaneously reducing undesirable side effects" (claim 1)	The side effects are those associated with acute administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic and teratogenic effects associated with the use of racemic albuterol that are caused directly by the S(+)-enantiomer of albuterol.	"Side effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.

# Exhibit 25

## US PATENT NO. 5,760,090

DISPUTED TERM (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEV'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"while reducing side effects associated with the administration of racemic albuterol" (claim 1)	The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Reducing those beta-adrenergic side effects and teratogenic effects associated with the administration of racemic albuterol that are caused directly by the S(+)-enantiomer of albuterol.	"Side effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.
"while simultaneously reducing undesirable side effects" (claim 1)	The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic and teratogenic effects associated with the use of racemic albuterol that are caused directly by the S(+)-enantiomer of albuterol.	"Side effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.

## Exhibit 25

## US PATENT NO. 5,844,002

DISPUTED TERM (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEY'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"inducing bronchodilation or providing relief of bronchospasm" (claims 1 and 10)	"Bronchospasm" means a contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen, which is not limited to bronchospasms associated with asthma. The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Treating asthma.	Treating asthma or an asthma attack.
"while reducing the concomitant liability of adverse effects associated with racemic albuterol" (claim 10)	The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Reducing those beta-adrenergic side effects and teratogenic effects associated with the administration of racemic albuterol that are caused directly by the S(+)-enantiomer of albuterol.	"Adverse effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.
"while simultaneously reducing said adverse effects" (claim 10)	The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic side effects and teratogenic effects associated with the use of racemic albuterol that are caused directly by the S(+)-enantiomer of albuterol.	"Adverse effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 ll. 28-31, 33-35.



# Exhibit 25

## US PATENT NO. 6,083,993

DISPUTED TERM (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEY'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"treating bronchospasm in a patient with reversible obstructive airway disease" (claim 1)	<p>"Bronchospasm" means "contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen."</p> <p>"Reversible obstructive airway disease" means "a respiratory disorder such as asthma, chronic bronchitis, and emphysema."</p>	Treating an asthma patient after the onset of an asthma attack (acute treatment).	Treating asthma or an asthma attack.
"preventing bronchospasm in a patient with reversible obstructive airway disease" (claim 10)	<p>"Bronchospasm" means "contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen."</p> <p>"Reversible obstructive airway disease" means "a respiratory disorder such as asthma, chronic bronchitis, and emphysema."</p>	Chronically treating a patient for asthma.	Preventing asthma or an asthma attack.

# **EXHIBIT 26**

**REDACTED**

# **EXHIBIT 27**

**REDACTED**